

**UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF MASSACHUSETTS**

In re: New England Compounding Pharmacy, Inc.,)	
)	
)	
)	Civil Action No. 1:13-md-02419(RWZ)
All Cases Involving Specialty Surgery Center and Dr. Kenneth Lister)	MDL No. 13-2419-RWZ
)	

**[PROPOSED] QUALIFIED PROTECTIVE ORDER REGARDING
PLAINTIFFS' STEERING COMMITTEE'S SUBPOENA OF
CUMBERLAND MEDICAL CENTER, INC.**

Pursuant to the Court's July 28, 2016 Order (Dkt. No. 3015), the Plaintiffs' Steering Committee ("PSC"), Cumberland Medical Center, Inc. ("CMC"), Specialty Surgery Center, PLLC, Dr. Kenneth Lister, and Kenneth Lister, M.D., P.C. (the "SSC Defendants"), and Jean Atkinson ("Ms. Atkinson") have, through counsel, agreed to the entry of this Qualified Protective Order Regarding Plaintiffs' Steering Committee's Subpoena of Cumberland Medical Center, Inc. ("QPO") pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and pursuant to regulations promulgated under the Health Insurance Portability and Accountability Act, as amended, to prevent unnecessary or unlawful disclosure or dissemination of confidential patient protected health information ("PHI"), financial information, and proprietary, confidential, and/or commercial information over potential protections that have not otherwise been waived, the Court ORDERS that the production and use of documents produced by CMC in response to PSC's subpoena proceed as follows:

DEFINITIONS

"Confidential Information" means documents containing proprietary or confidential business information of CMC and/or SSC, documents containing PHI or financial information of

patients who are not plaintiffs in the MDL matter, or documents containing PHI or financial information of CMC employees.

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, codified primarily at 18, 26 & 42 U.S.C.

“PHI” means protected health information, as that term is used in HIPAA and the Privacy Standards defined in 45 C.F.R. § 160 & 164.

“Signatories” means CMC, the PSC, the SSC Defendants, and Ms. Atkinson, their attorneys, and their non-attorney staff and experts retained by any party, and all non-parties that a court may subsequently recognize as a signatory of this Qualified Protective Order.

PROTOCOLS FOR REVIEW AND PRODUCTION

1. CMC shall produce the electronic repositories (seven hard-drives) purchased from Specialty Surgery Center, PLLC (“SSC”), to LogicForce Consulting, LLC (“LogicForce”), as set forth in the agreed Protocols for Review of Certain Responsive Hard-Drives in Cumberland’s Possession (“Review Protocols”), which are attached as Exhibit 1 hereto and incorporated by reference. LogicForce has executed a Business Associate Agreement with CMC for the purposes of conducting a forensic inspection and analysis of the hard-drives in accordance with the Review Protocols. By providing said electronic repositories to LogicForce, CMC is not waiving any claims of privilege, including attorney-client communication, or any other state or federal privilege that may be applicable and could have been asserted in the absence of disclosure to LogicForce.

2. In accordance with the terms and provisions set forth in the Review Protocols LogicForce will conduct a forensic analysis and inspection of the seven-hard drives, and shall

perform an electronic discovery retrieval of records responsive to certain search terms agreed to by Cumberland and the PSC. As set forth in the Review Protocols:

- CMC shall have an exclusive initial opportunity to review forensic reports and responsive materials for Confidential Information (including privileged material); and
- After CMC has completed its review, (a) the SSC Defendants shall have the opportunity to review responsive records only for the purpose of identifying information over which they claim privilege under the Tennessee Peer Review Privilege (“PRP”) and the Tennessee Quality Improvement Committee Privilege (“QICP”), and (b) Ms. Atkinson shall have the opportunity to review responsive records for documents protected by her personal attorney-client privilege and work product privileges, under the conditions set forth herein

3. To the extent any documents containing PHI or other Confidential Information are produced to Signatories, Signatories agree to be bound by this Order.

HIPAA TERMS AND LIMITATIONS

4. The Signatories are familiar with HIPAA and the Privacy Standards.

5. The Signatories recognize that PSC’s subpoena issued and served upon CMC seeks information that may include PHI.

6. Accordingly, the Signatories recognize that documents containing PHI produced by CMC may be further disseminated and transmitted to the Signatories, third-parties, and non-parties.

7. Notwithstanding federal or state law limiting the Signatories and CMC’s authority to disclose PHI, CMC is permitted to release all PHI in its possession, which is currently stored on seven hard-drives in the possession, custody, and control of CMC, subject to the Review Protocols, in response to the subpoena issued by the PSC on CMC on January 29, 2016, provided that the PHI is relevant to the issues presented in this litigation.

8. The Signatories are permitted to use the PHI in any manner that is reasonably connected with this lawsuit. This includes, but is not limited to, disclosures to the parties, their attorneys of record, the attorney's firms (*i.e.*, attorneys, support staff, agents, and consultants) the parties' insurers, experts, consultants, court personnel, court reporters, trial consultants, jurors, and other entities involved in the litigation process. The Signatories agree not to use or disclose any PHI produced by CMC in response to PSC's subpoena in this lawsuit for any other purpose or in any other proceeding.

9. The Signatories agree that within 90 days of the issuance of a final order, or the extinguishment of all appeals, all Signatories that obtained PHI produced by CMC in response to PSC's subpoena during the course of this lawsuit shall return to CMC or shall destroy said PHI.

OTHER CONFIDENTIAL MATERIAL

11. The Signatories agree to be bound to the Third Amended Protective Order (Dkt. No 814) for all materials and/or documents (other than PHI) designated as confidential information and produced pursuant to this Order.

A copy of this Protective Order shall be served on all counsel within ____ days of its entry.

So ORDERED on this ____ day of _____, 2016.

JENNIFER C. BOAL
United States Magistrate Judge

JOINTLY AGREED TO AND ENTERED BY:

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/s/ Matthew H. Cline
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Attorney for Cumberland Medical Center

EXHIBIT 1

JOINT PROTOCOLS FOR REVIEW OF CERTAIN RESPONSIVE HARD-DRIVES

IN CUMBERLAND'S POSSESSION

On January 29, 2016, the Plaintiffs' Steering Committee ("PSC") in MDL 2419 served a subpoena to Cumberland Medical Center, Inc. ("Cumberland"). Among other things, the subpoena requested that Cumberland make available to the PSC for forensic inspection and analysis all electronic repositories that Cumberland received from Specialty Surgery Center, PLLC ("SSC") arising from Cumberland's acquisition of SSC's assets in June 2013 (the "Asset Purchase").

Cumberland has identified eight hard-drives, seven (7) hard-drives (the "Hard-Drives") of which the PSC has indicated it has a current interest and intends to examine. Four of those Hard-Drives were not placed in operation following the Asset Purchase (the "Non-Operational Hard-Drives"). The other three Hard-Drives were placed in operation by Cumberland following the Asset Purchase (the "Operational Hard-Drives"). The PSC intends to conduct a forensic diagnostic review of the data on the Hard-Drives (the "Forensic Review") and to review the content of files on the Hard-Drives (the "E-Discovery Review"). The Forensic Review and E-Discovery Review may run concurrently.

Pursuant to the Court's July 28, 2016 Order at Docket No. 3015, and in addition to initial exclusive review by Cumberland, (a) Specialty Surgery Center, PLLC, Dr. Kenneth Lister, and Kenneth Lister, M.D., P.C. (the "SSC Defendants"), shall have the opportunity to review information on the computers for the Tennessee Peer Review Privilege ("PRP") and the Tennessee Quality Improvement Committee Privilege ("QICP"); and (b) Ms. Atkinson shall have the opportunity to review the information on the computers for documents protected by her personal attorney-client privilege and work product privileges, under the conditions set forth herein.

The PSC has approved the use of LogicForce Consulting LLC ("LogicForce") to conduct imaging, forensic review, data processing, data hosting, and other services associated with the Hard-Drives. Without waiving its right to move for cost-shifting at a later point, the PSC shall incur the costs for LogicForce's services. The PSC acknowledges that Cumberland takes the position that any costs associated with the Forensic Review and E-Discovery Review associated with LogicForce should be borne by the PSC as requiring Cumberland to bear such costs constitutes an undue burden.

Subject to the executed Business Associate Agreement between Cumberland and LogicForce concerning HIPAA-protected information, the protocols set forth herein are agreed to by and between Cumberland, the PSC, the SSC Defendants, Ms. Atkinson, and LogicForce on this 4th day of August 2016.

Imaging

Within three business days of the entry of a Qualified Protective Order by the Court, Cumberland shall make available to LogicForce the three Operational Hard-Drives for on-site imaging. With respect to the Non-Operational Hard-Drives, Cumberland may either (a) hand-deliver those drives to LogicForce on the same date that LogicForce conducts its on-site imaging of the Operational Hard-Drives, or (b) send those drives via FedEx or other secure means for delivery within three business days of the entry of a Qualified Protective Order by the Court. LogicForce will image the Non-Operational Hard-Drives, and return the Non-Operational Hard-Drives back to Cumberland expeditiously. The parties shall refer to the date of receipt or access to both sets of hard drives as the "Receipt Date."

Forensic Review

Forensic Review Phase I

LogicForce will conduct a forensic examination of the files on all seven Hard-Drives. The findings reported from any forensic examination conducted by LogicForce shall not include any internal document data or content, including any information potentially protected by HIPAA. LogicForce's report may include metadata such as file names, the date and time a document was created, the dates and times a document was accessed, the dates and times a document was modified, HASH values, file size, file path or physical location of the data on the source media, and file permissions, as well as operating system artifacts such as registry information.

- Within 7 days of the Receipt Date, LogicForce shall supply the report to Cumberland so that Cumberland may conduct a review and redact or remove any privileged, confidential, proprietary, and/or HIPAA materials.
- Within 2 days thereafter, Cumberland shall complete its review, and it shall provide a privilege log of any redacted or removed material from the findings report.
- Within 2 days thereafter, the SSC Defendants and Ms. Atkinson shall have the opportunity to review the report, and to redact or remove any information covered by an applicable privilege, and they shall each provide a privilege log of any redacted or removed material from the findings report
- Once these reviews have been completed, the findings report will be provided to the PSC. The PSC shall have 2 days thereafter to complete its review and identify documents subject to the Phase II review.

Forensics Review Phase II

After receiving the report, the PSC will notify LogicForce in writing of all files the content of which the PSC intends to inspect for purpose of the Forensic Review. The PSC shall identify the files using the file name, HASH value, and full path of each file to be reviewed.

Before permitting the PSC to review any file content as part of the Forensic Review, LogicForce shall produce the identified files to counsel for Cumberland for inspection.

- Within 30 days, Cumberland will review the identified files for any privileged, confidential, proprietary, and/or HIPAA information and have any such files redacted or removed. Upon receiving Cumberland's request to redact or remove files, LogicForce will immediately remove or redact such files (as appropriate) and make available to the SSC Defendants and Ms. Atkinson any files over which Cumberland does not assert a claim of privilege, confidentiality, proprietary information, and/or HIPAA protection.
- Within 7 days of receiving access to the files, (a) the SSC Defendants shall identify documents or materials over which they assert the PRP or QICP, and (b) Jean Atkinson shall identify documents or materials over which she asserts personal attorney-client privilege and work product protection. Upon receiving CMC's, the SSC Defendants' and Ms. Atkinson's requests to redact or remove files, LogicForce will immediately remove or redact such files (as appropriate) and make available to the PSC all remaining files or content.
- Within five business days of their respective review completion dates, parties invoking privilege shall provide a privilege log for all materials they have asserted should be withheld or redacted.

Forensic Phase 3 – Additional Examination

If the PSC determines that additional forensic review is warranted, the procedures set forth in Forensic Phase 1 and Forensic Phase 2 above shall apply.

E-Discovery Review

LogicForce will search the Hard-Drives for files containing the search terms attached as Exhibit A hereto and load all such files onto a password-protected review platform.

- Within 7 days of the Receipt Date, Cumberland will be granted exclusive access to those files to identify any privileged, confidential, proprietary, and/or HIPAA protected information so that those files are redacted or removed. To the extent practicable, with Cumberland's assistance LogicForce will utilize software to help identify to Cumberland files that may contain HIPAA-protected information.

Non-Operational Hard-Drives

With respect to files derived from the Non-Operational Hard-Drives that are placed on the review platform:

- Within 30 days of receiving access, Cumberland shall redact or remove any privileged, confidential, proprietary, and/or HIPAA materials, and LogicForce redact or remove all items marked by Cumberland as privileged, confidential, proprietary, and/or HIPAA materials and then shall make available to the SSC Defendants and Ms. Atkinson all documents and material not already designated by Cumberland. Within 5 business days of completion of its review of the non-operational Hard-Drives, Cumberland shall provide a privilege log to the PSC.
- Within 14 days of receiving access, (a) the SSC Defendants shall identify documents or materials over which they assert the PRP or QICP, and (b) Jean Atkinson shall identify documents or materials over which she asserts personal attorney-client privilege and work product protection. To the extent practicable, the SSC Defendants and Ms. Atkinson agree that LogicForce may make available to the PSC, on a rolling basis, those files that the SSC Defendants and Ms. Atkinson have already reviewed and indicated are not subject to protection on the grounds allowed by the Court in its July 28, 2016 Order.
- Thereafter, except as otherwise set forth herein, the PSC can inspect all remaining files independently without further notice to Cumberland, the SSC Defendants, or Ms. Atkinson.

Operational Hard-Drives

With respect to the Operational Hard-Drives, Cumberland asserts that those Operational Hard-Drives contain information that is not reasonably likely to lead to the discovery of evidence admissible with respect to the claims at issue in MDL 2419, such as records relating to Cumberland's daily business operations from 2014 forward. The PSC presumptively does not seek access to files dated January 1, 2014 or later. Without prejudice to the PSC's right to seek review of materials dated January 1, 2014 or later, the datasets for review shall only include files created on or before December 31, 2013. The same deadlines and conditions set forth above with respect to the Non-Operational Hard Drives shall otherwise apply.

Additional Time For Review

The parties have developed this protocol using best efforts and reasonably believe that the time periods herein are manageable and appropriate. However, all parties acknowledge that the sizes of the dataset returned from the Forensic and E-Discovery Review are unknown at this time. Although all parties agree to use best efforts to complete reviews in the applicable time periods, should it become necessary due to size of data or other constraints to request additional time, any party may request an extension on the deadline with the Court, and by agreeing to the above

deadline no parties waive such right to request such relief. It is noted and agreed to by all parties that counsel for CMC are in trial August 22 – September 6 and will not be able to review materials during that time.

Claw Back Provision

To the extent that Cumberland, the PSC, or LogicForce ascertain that any files may contain information over which Cumberland has a claim of privilege, confidentiality, or proprietary information, and/or information that is HIPAA-protected and has been or may have been made available to the PSC in spite of these Protocols, the party that identifies that issue shall notify the other parties in writing immediately. Upon notice, LogicForce shall segregate those files, and will not permit the PSC to review those files further until Cumberland has an opportunity to review them and to assert any applicable protections under HIPAA or to assert a claim of confidentiality, proprietary information, and/or privilege held by Cumberland. The parties are to segregate and refrain from further review of such material until Cumberland has been given an opportunity to assert a privilege, confidentiality, proprietary information, and/or protection from disclosure under HIPAA, which it shall do within 5 business days of notice of the issue. If there is no dispute as to privilege or confidentiality, the document(s) subject to the claw back provision shall be immediately destroyed or returned to Cumberland. If there is a dispute as to privilege, the document(s) will remain segregated and will not be reviewed further until the dispute over privilege or confidentiality is resolved.

To the extent that the SSC Defendants or the PSC ascertain that documents or materials over which they assert the PRP or QICP has been or may have been made available to the PSC in spite of these Protocols, the party that identifies that issue shall notify the other party or parties in writing immediately. The PSC agrees to segregate and refrain from further review of such material until the SSC Defendants have been given an opportunity to assert a privilege, confidentiality, proprietary information, and/or protection from disclosure under HIPAA, which it shall do within 5 business days of notice of the issue. If there is no dispute as to privilege or confidentiality, the document(s) subject to the claw back provision shall be immediately destroyed or returned to the SSC Defendants. If there is a dispute as to privilege, the document(s) will remain segregated and will not be reviewed further until the dispute over privilege or confidentiality is resolved.

To the extent that Ms. Atkinson or the PSC ascertain that documents or materials over which she asserts personal attorney-client privilege and work product protection has been or may have been made available to the PSC in spite of these Protocols, the party that identifies that issue shall notify the other party in writing immediately. The PSC agrees to segregate and refrain from further review of such material until Ms. Atkinson has been given an opportunity to assert a

privilege, confidentiality, proprietary information, and/or protection from disclosure under HIPAA, which it shall do within 5 business days of notice of the issue. If there is no dispute as to privilege or confidentiality, the document(s) subject to the claw back provision shall be immediately destroyed or returned to the SSC Defendants. If there is a dispute as to privilege, the document(s) will remain segregated and will not be reviewed further until the dispute over privilege or confidentiality is resolved.

Dated: August 4, 2016

Signatures on Following Page

Plaintiffs' Steering Committee

By: _____
Benjamin A. Gastel

Cumberland Medical Center, Inc.

By: _____
Rachel Park Hurt

SSC Defendants

By: _____

Jean Atkinson

By: _____
Jean Atkinson

Logic Force LLC

By: _____
Jim Kempvane

EXHIBIT A – Search Terms and Exclusion Criteria

Date Range: 1/1/2011-12/31/2013

Document/File Types: All Microsoft office documents, emails, pdfs, .wps, .oxps, .pub, .txt, .rtf, .rtfd, .asc, and .dat file types

08-12-10

Atkinson and supplier or infection

“Approved Medication*”

Attorney

betamethasone

Boston

Business and associate and agreement

Calisher

Chris

Cline

CJ

Compound*

Contamin*

Cura*

Depo

depomedrol

depo-medrol

“Effective Date”

Epidural

“Executive Committee”

FDA

FBI

Formulary

Fung*

Giamei

Gideon

Governing body

Hammervold

Investigat*

Lawyer*

Kainer

Massachusetts

Matt

“Medical Director”

“Medication Management”

Meningitis

Methylprednisolone

MPA

Metoprolol

NECC

Outbreak

"Patient list"

Pfizer

Pharmacy

Prescription

Policy

Recall*

Revision

Simpson

Steroid

SVMIC

Tardio

"US Attorney"

"United States Attorney"